IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
S. Rao CHERUKURI	)	Group Art Unit: 1618
	)	
Application Number: 09/982,093	)	Examiner: B. Fubara
	)	
Filed: October 19, 2001	)	Confirmation No. 6757
	)	
For: DRUG DELIVERY SYSTEMS		

MAIL STOP ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICANT'S STATEMENT OF THE INTERVIEW

Sir:

Applicant and applicant's representatives had a telephonic interview with Examiner Fubara on 25 November 2009. Applicant's representative Ricardo J. Moran; Applicant S. Rao Cherukuri; and Mr. Revanth Mutyala, Associate Director, Product Development, Capricorn Pharma Inc. all participated in the interview.

The purpose of the interview was to discuss the Examiner's Amendment to claim 40 to replace "povidone k30" with "polyvinylpyrrolidone k30" and "plasdone k29/32" with "polyvinylpyrrolidone k29/32." The following statement describes the substance of the interview as it was understood by Applicant and Applicant's representative.

During the telephonic interview (or shortly thereafter) Mr. Mutyala provided the Examiner with technical information regarding polyvinylpyrrolidone(s) submitted herewith as Exhibit A. The technical information includes a copy of page 392 from the Handbook of Pharmaceutical Excipients (2d ed., Pharmaceutical Press 1994) (hereinafter "the Handbook"). The second and third pages of Exhibit A contain the manufacturer (ISP corporation) specification of Plasdone K29/32, where the third page contains the limits of the K-value for Plasdone K29/32, which range from 29 to 32. Moreover, the third page contains a statement, at

the bottom of the page, that the "[m]aterial meets the requirements for Povidone in current US, European and Japanese Pharmacopeias." The fourth through the seventh page of Exhibit A are taken from the USP 31 Monograph for Povidone. In those pages are detailed, among other things, the limits of the K-value for Povidone K-30.

Page 392 from the Handbook shows that "Povidone" and "Plasdone" are names that are synonymous with "polyvinylpyrrolidone." *See*, page 1, Exhibit A, item "2. Synonyms." Further, on the same page, under item 4, the document states that povidone is "characterized by its viscosity in aqueous solution, relative to that of water, expressed as a K-value, ranging from 10-120" and that the K-value "is calculated using Fikentscher's equation" or alternatively using the equation:

$$K\text{-}value = \frac{\sqrt{300c\log z + (c + 1.5c\log z)^2} + 1.5}{0.15c + 0.03c^2}$$

where z is the relative viscosity of the solution of concentration c, k is the K-value x 10^{-3}, and c is the concentration in % w/v.

The seventh page of Exhibit A gives a related equation for the calculation of the K-value:

$$K\text{-}value = \frac{\left[\sqrt{300c\log z + (c + 1.5c\log z)^2} + 1.5c\log z - c\right]}{(0.15c + 0.003c^2)}$$

where c is the weight in grams (on an anhydrous basis) of the specimen tested in each 100.0 mL of solution and z is the viscosity of the test solution relative to that of water.

The synonym information on page 392 of the Handbook makes it clear that "povidone k30" and "plasdone k29/32" would be synonymous with "polyvinylpyrrolidone k30" and "polyvinylpyrrolidone k29/32." In addition, the "k30" and the "k29/32" that follow the "polyvinylpyrrolidone" simply refer to the K-value of the polyvinylpyrrolidone. In the case of "k29/32," that simply means that the K-value ranges from 29 to 32. *See* page 3 of Exhibit A. As discussed above, the K-value characterizes the viscosity of the polyvinylpyrrolidone in aqeuous solution, relative to that of water. Accordingly, part d) of claim 40, as amended in the

Examiner's amendment that accompanied the Supplemental Notice of Allowability mailed 10 December 2009 should be construed as follows:

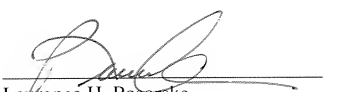
"at least one binder which is polyvinylpyrrolidone with a K-value of 30 or a polyvinylpyrrolidone with a K-value from 29 to 32."

It is believed that no fees are necessary in connection with this submission. However, in the event that the U.S. Patent and Trademark Office determines that fees are due, the Commissioner is hereby authorized to debit such fee to the undersigned's Deposit Account No. **50-0206**.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Dated: January 29, 2009

By: 

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